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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,440

03/25/2004

Ashish Varma

PA1555 CIP2

6972

28390 7590 03/18/2008
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IP LEGAL DEPARTMENT
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

03/18/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/808,440	Applicant(s) VARMA ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Amendment 1/17/08 has been entered.

Claims 1-14 are present for examination.

The arguments regarding claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **“a guide member slidably coupled to the proximal shaft for providing access to the guidewire lumen via the longitudinal cut”** of claims 1 and 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation “a guide member slidably coupled to the proximal shaft for providing access to the guide-wire lumen via the longitudinal cut” is vague. Does Applicant mean that the guide member is as a guide-wire?

For examiner purpose, Examiner interprets the guide member as a guide-wire.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardsley et al. (US 6,004,310) in view of Crittenden et al. (US 4,988,356), McNeil (US 3,972,529).

Bardsley discloses a catheter comprising: a proximal shaft defining a guide wire lumen 110; and inflation lumen 120; wherein the inflation lumen is actuate shaped; a support strip/reinforcement member /joint member 135 or 225 or 330 (see Figs. 2-5), (see explain below and in claims 3, 5-7 and 14); a guide member (guide-wire) slidably coupled to the proximal shaft.; a support strip/reinforcement member /joint member 135 disposed adjacent to the inflation lumen 120; wherein the reinforcement member is entirely embedded within the wall of the proximal shaft and radially disposed between the inflation lumen and the outer surface 125 of proximal shaft. It is noted that the element 135 can be a plank-like support strip or

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joint member also. The element 135 may be of a variety of different configuration designed, (such as a plank-like support strip or joint member) to impart the desired stiffness to the catheter shaft section and prevent kinking or undistorted (col. 6, lines 14-20). Furthermore, Applicant admitted that it is well-known in the art that the reinforcement means provided in catheter shaft in order to reinforce the proximal shaft (Specification, para [0056]).

Bardsley does not disclose that the inflation lumen has a longitudinal cut extending radially to the shaft of the guide wire lumen.

Crittenden discloses a catheter with a longitudinal cut (Figs. 2, 5, cut is 28) extending radially from an outer surface of the shaft to the guide wire lumen (col. 2, lines 30-35).

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Bardsley with a longitudinal cut, as taught by Crittenden, in order to provide a means for inserting or removing an object, such as a guide wire. Similarly, it is well-known in the art that the longitudinal cut that extends along the catheter shaft and extends radially from the guide-wire lumen to an exterior surface of a catheter shaft (Applicant Admitted Prior Art, see Specification, para [0016]).

McNeil alternatively teaches that the strength, durability and stiffness characteristics of elongated tube, can be increased dramatically by the lengthwise incorporation of continuous unidirectional strips/plank-like support strip/joint member 12, 16, 19 which are integrated along the outer surface of the shaft/tube 11 (col. 1, lines 55-65, col. McNeil further discloses that the reinforced cylindrical tubular elements are excellent structural uses where lightness of weight and high strength are required (col. 4, lines 8-12). It is noted that the catheter device is well-known formed of lightness of weight and need high strength to prevent kinking when it inserted into the body/vessel. Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Bardsley with strips/joint member, as taught by McNeil, in order to increasing the strength, durability and stiffness characteristics of the tubular tube. Also, it would have been obvious to a person of ordinary skill in the art to try adding the strips of McNeil in to the catheter device in an attempt to provide an improved strength,

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durability and stiffness of catheter/elongated/tubular tube, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding claims 3, 5-7 and 14, since the Applicant does not clearly explain details what the special purpose to have the support strip 436A, B; a joint member 474A, 474B, (in Fig. 4C of the Specification) disposed in the proximal shaft at a circumferential location that is between and end of the support strip and an end of the curved reinforcement member. Therefore, one skill in the art would recognize that the support strip or join member of Applicant have same function as reinforcing means 435 with under different shape and located in different position. In other words, the reinforcing means, support strip and joint member are same element with different names and different shapes.

Meanwhile, Bardsley further clearly discloses that the support member 135 may be variety of different materials and configurations designed to impart the desired stiffness to the catheter shaft section and in particular ensure that the cross-section shape of the lumen remains substantially undistorted as in undergoes the high flexure encountered during traversal of the sharp bends in the vascular pathway (col. 6, lines 14-23). Therefore, it would have been an obvious matter of design choice to provide a joint member or a plank-like support strip, since applicant has not disclosed that joint member or a plank-like support strip solves any stated problem or is for any particular special purpose and it appears that the invention would perform equally well with the reinforcing means of Bardsley or the strip of McNeil.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the support strip or join as recite in claims 1-3, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding claims 4 and 10, Bardsley in view of Crittenden and McNeil disclose the claimed invention except for the joint member constructed of one of a polyolefin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the polyolefin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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Regarding claims 8-9, similar to the rejection of claims 1-3 above.

Regarding claims 11-13, the support strips and the reinforcing member is selected from the group of stainless steel, titanium, tungsten, and Nitinol or high modulus polymer (col. 6, lines 33-42 of Bardsley). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the support strips and the reinforcing member made of metal or stainless steel, or high modulus polymer as listed in claims 11-12, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763